K113206

Dräger

FEB 17 2012

510(k) Summary
acc. to 807.92

Submitter's Name and Address: *Draeger Medical Systems, Inc*
3135 Quarry Road
Telford, PA 18969 USA

Contact Person: *Bryan Overton*
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Date submission was prepared: *2011-10-31*

Device Name:

Proprietary Name:	*NanoBlu™ 500*
Common Name:	*Phototherapy Light, Bili Light*
Classification Name:	*Neonatal Phototherapy Unit*
Regulation Number:	*21 CRF 880.5700*
Product Code:	*LBI*
Class:	*2*

Legally Marketed Device Identification: *Natus® Blue Light Phototherapy, K022196*

Device Description:
The Dräger NanoBlu 500 is an LED phototherapy light. It consists of an LED module with 5 LEDs and a fan, a microprocessor controller, and an alphanumeric display and keyboard. The display and keyboard are used to program the functions of the light.

The Dräger NanoBlu 500 is available in two versions, the hood mount and the trolley mount. The hood mount version has suction cups on the bottom that are used when placed on the top of an incubator.

The trolley mount version is mounted on a rolling trolley to allow use above an incubator or radiant warmer. The trolley consists of a base supported by three 2 in (5.08 cm) castors. A column, with an adjustable and articulating arm, connects them. Both of these features allow the light to be positioned for optimum light over the patient.

There are no single-use components or accessories for the NanoBlu™ 500.

Intended Use:
The Dräger NanoBlu 500 LED Phototherapy Light is intended to treat neonatal hyperbilirubinemia by providing phototherapeutic light to the body of the patient. It is intended for use on the recommendation and under the supervision of

healthcare professionals. Additionally, this product can be used with an under-baby phototherapy light to increase patient coverage.

Predicate Devices:

510(k) Number	Device Name
K022196	*Natus Blue Light Phototherapy Unit*

Substantial Equivalence:

The NanoBlu™ 500 and the Natus® Blue Light Phototherapy Unit have the same intended use (treatment of hyperbilirubinemia), use the same operating principle (delivery of light to degrade bilirubin), and are similar in their hardware configuration. See the Comparison Table below for details.

Summary Comparison Table
NanoBlu 500 vs. Natus® Blue Light

Feature	NanoBlu 500	Natus® Blue Light (K022196)
Intended Use	For the treatment of neonatal hyperbilirubinemia	For the treatment of neonatal hyperbilirubinemia
Target population	Neonates	Neonates
Physical Design		
Type	Freestanding device	Freestanding device
Mounting hardware	Roll Stand, 3 legs w/casters, 3 locking	Roll Stand, 5 legs w/casters, 2 locking
Light attachment	Lights mounted in enclosure	Lights mounted in enclosure
Performance		
Light source	Light Emitting Diodes (LED)	Light Emitting Diodes (LED)
Wavelength	400-550 nm	400-550 nm
Intensity	Minimum 40 µW/cm2·nm	35 ± 3.5 pW/cm2/nm @ High setting
Electrical Requirements		
Operating Voltage	90 VAC to 240 VAC	85 VAC to 264 VAC
Standards and Safety		
Electrical Safety	IEC 60601 -1 and 1-1 -2 UL 60601-1 CSA/CAN C22.2 601.1 IEC 60601-2-50	EN 60601 -1 and 1-1 -2 UL 2601-1 CSA/CAN C22.2 601.1 EN 60601 -2-50

Summary of Nonclinical Testing

This submission includes the results of testing prototype devices to specifications, spectral characterization of the LED light source, and an analysis of the potential optical radiation hazard of the blue LED light source.

Testing was also performed to assess compliance to the following standards:

- IEC60601-1, Medical Electrical Equipment, Part 1: General Requirements for Safety
- UL60601-1, Medical Electrical Equipment, Part 1: General Requirements for Safety
- IEC60601-1-2, Medical Electrical Equipment, Part 1-2: General Requirements for Safety Collateral Standard: Electromagnetic Compatibility
- IEC60601-2-50, Medical Electrical Equipment, Part 2: Particular requirements for the Safety of Infant Phototherapy Equipment

Clinical Tests – Not Applicable

The results were as expected and no new issues of safety or effectiveness were raised as a result of the nonclinical testing.

Conclusions

Based on the data and information presented in this submission, the NanoBlu™ 500 Phototherapy Light is substantially equivalent to the currently legally marketed Natus® Blue Light Phototherapy Unit manufactured and distributed by Natus Medical, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Bryan Overton
Director, Quality Assurance & Compliance
Draeger Medical Systems, Inc.
3135 Quarry Road
Telford, Pennsylvania 18969

FEB 17 2012

Re: K113206
Trade/Device Name: NanoBlu™ 500
Regulation Number: 21 CFR 880.5700
Regulation Name: Neonatal Phototherapy Unit
Regulatory Class: II
Product Code: LBI
Dated: January 26, 2012
Received: January 27, 2012

Dear Mr. Overton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

Indications for Use

510(k) Number (if known): _____

Device Name: NanoBlu™ 500_____

Indications for Use:

The Dräger NanoBlu 500 LED Phototherapy Light is intended to treat neonatal hyperbilirubinemia by providing phototherapeutic light to the body of the patient. It is intended for use on the recommendation and under the supervision of healthcare professionals.

Prescription Use ____X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

2/15/12

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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